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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,000	02/23/2005	Yaeta Endo	3190-071	6735

33432 7590 03/12/2007

KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,000	ENDO ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9 and 12-16 and 18-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In the amendment of 1/18/05, Claims 10, 11 and 17 were cancelled.

2. Claims 1-9 and 12-16 and 18-28 are all the pending claims for this application and all the claims subject to restriction.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a single chain antibody comprising a linker where the linker comprises a labeling substance. The antibody is not limited as to where the linker part should occur within the structure of the single chain antibody or how the linker relates structurally or functionally to the labeling substance. In view of this, the technical feature is not special because Luo et al. (J. Biotechnol. 65:225-228 (1998); cited in the IDS of 1/18/05) and Zhang et al. (Can. Res. 55:3584-3591 (1995); cited in the IDS of 1/18/05) disclose antibodies that read on the technical feature. Luo discloses a scFv with a C-terminal extension comprising a biotin mimetic sequence (BMS) or c-Myc-BMS as an in vitro diagnostic. Zhang discloses Vh and VL chains joined by a (Gly4Ser)3 linker and further biotinylated. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, 20, 24 and 28, drawn to a single chain antibody carrying a labeling substance in a linker part of the antibody.

Group II, claim(s) 12-16, 18, 19, drawn to DNA encoding a heavy and light chain having the ability to bind a specific antigen and being linked through a DNA encoded linker having the ability of binding to a labeling substance, and a method of using the DNA to produce the labeled single chain antibody.

Group III, claim(s) 21-23 drawn to a method for producing an immobilized single chain antibody carrying a labeling substance in a linker part of the antibody and contacting the antibody onto a reaction plate comprising a plurality of regions having on the surface a substance that binds to the labeling substance of the antibody.

Group IV, claim(s) 25 and 26, drawn to a method for analyzing an antigen-antibody reaction comprising reacting a test substance with an immobilized single chain antibody and analyzing the binding ability of the test substance with the single chain antibody.

Group V, claim(s) 27, drawn to a reagent kit comprising a reagent for use in an assay for measuring antigen-antibody reaction.

5. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Luo et al. and Zhang et al. the groups are not so linked as to

form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

6. Inventions of Groups I, II and V represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Group I is a single chain antibody comprising a linker, Group II is a DNA and Group V is a reagent in a test kit for analyzing binding between an antigen and antibody. He claim is indefinite with respect to the structure or function of the kit reagent, but the specification provides examples of a kit reagent as "a tool for diagnosing and analyzing the presence or absence of a human autoantibody, a cancer cell specific antigen and the like." The polynucleotide is different in structure from the scFv of Group I in that the polynucleotide is made up of nucleic acids and the scFv is made up of amino acids. The polynucleotide is made by nucleic acid synthesis while the scFv is made by translation of RNA. If, for example, a kit reagent comprises a label, then the label could be biotin or avidin or fluorescein or a chromogenic dye, etc., thus any one of these reagents is not overlapping in structure or function with the scFv of Group I or the DNA of Group II. The examination of all groups would require different searches in the U.S., international and foreign patent literature and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II and V are patentably distinct.

7. Inventions of Groups III and IV differ in the method objectives, method steps and parameters, intended populations and in the reagents used. The method of Group III requires a single chain antibody carrying a labeling substance in a linker part of the

antibody and a reaction plate comprising a plurality of regions having on the surface a substance that binds to the labeling substance of the antibody, and contacting the antibody and the plate in order to produce an immobilized antibody; and the method of Group IV requires a test substance and an immobilized single chain antibody, and contacting both in order to analyze the binding ability of the test substance with the single chain antibody to determine whether an antigen-antibody reaction has occurred. The examination of all groups would require different searches in the U.S., international and foreign patent literature and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III and IV are separate and distinct in having different method steps, intended populations and different endpoints and are patentably distinct.

8. Inventions of product Group I (antibody) and Groups III and IV (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the scFv of Group I can be used in a materially different method such as to purify the antigen such as by affinity chromatography in addition to the materially different methods of Groups III and IV.

9. The product of Group II is not disclosed as being capable of use with the methods of Groups III and IV.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER